

SYSTEM AND METHOD OF CHARACTERIZING VASCULAR TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit pursuant to 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Nos. 60/406,183, filed August 26, 2002, 60/406,254, filed August 26, 2002, 60/406,148, filed August 26, 2002, 60/406,184, filed August 26, 2002, 60/406,185, filed August 26, 2002, and 60/406,234, filed August 26, 2002, all of which are incorporated herein, in their entirety, by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to vascular tissue, or more particularly, to a system and method of using backscattered data and known parameters to characterize vascular tissue.

2. Description of Related Art

The present invention relates to the intra-vascular ultrasound (IVUS) analysis arts. It finds particular application to a system and method for quantitative component identification within a vascular object including characterization of tissue. It should be appreciated that while the present invention is described in terms of an ultrasonic device, or more particularly the use of IVUS data (or a transformation thereof) to characterize a vascular object, the present invention is not so limited. Thus, for example, using backscattered data (or a transformation thereof) to characterize any tissue type or composition is within the spirit and scope of the present invention.

Ultrasonic imaging of portions of a patient's body provides a useful tool in various areas of medical practice for determining the best type and course of treatment. Imaging of the coronary vessels of a patient by ultrasonic techniques can provide physicians with valuable information. For example, the image data may show the extent

of a stenosis in a patient, reveal progression of disease, help determine whether procedures such as angioplasty or atherectomy are indicated or whether more invasive procedures may be warranted.

In a typical ultrasound imaging system, an ultrasonic transducer is attached to the end of a catheter that is carefully maneuvered through a patient's body to a point of interest such as within a blood vessel. The transducer may be a single-element crystal or probe that is mechanically scanned or rotated back and forth to cover a sector over a selected angular range. Acoustic signals are then transmitted and echoes (or backscatter) from these acoustic signals are received. The backscatter data can be used to identify the type or density of a scanned tissue. As the probe is swept through the sector, many acoustic lines are processed building up a sector-shaped image of the patient. After the data is collected, an image of the blood vessel (i.e., an IVUS image) is reconstructed using well-known techniques. This image is then visually analyzed by a cardiologist to assess the vessel components and plaque content.

Typically, the ultrasonic image data is transferred to a VHS videotape, digitized and then analyzed. This process, however, loses image resolution since the videotape typically has a lower resolution than the originally collected backscatter data. Losing image resolution may result in an inaccurate evaluation of a vessel and its plaque content. Furthermore, certain image characteristics like brightness and contrast will be different for different patients or could vary for the same patient if the cardiologist varies the settings on the IVUS console. The images that are recorded on the videotapes are the same images viewed on the IVUS console screen and, thus, subject to the settings on the console. Since plaque (or tissue type) is identified by its appearance on the screen, errors may occur in the analysis if the screen settings have been modified. Another drawback is that certain information (e.g., tissue composition, etc.) cannot readily be discerned from an IVUS image (at least not to any degree of certainty). Thus, it would be advantageous to have a system and method of characterizing and/or imaging a vascular object that overcomes at least one of these drawbacks.

SUMMARY OF THE INVENTION

The present invention provides a system and method of using backscattered data and known parameters to characterize vascular tissue. Embodiments of the present invention operate in accordance with an ultrasonic device and a computing device comprising a characterization application and a database. Specifically, the ultrasonic device (e.g., intra-vascular ultrasound (IVUS) console and IVUS catheter) is used to acquire RF backscattered data (i.e., IVUS data) from a blood vessel. For example, a transducer may be attached to the end of a catheter and carefully maneuvered through a patient's body to a point of interest. The transducer is then pulsed to acquire echoes or backscattered signals (i.e., IVUS data) reflected from the tissue of the vascular object. The IVUS data is then transmitted to the computing device and used (either by the computing device or the IVUS console) to create an IVUS image.

In a first embodiment of the present invention, the characterization application is adapted to receive and store characterization data (e.g., tissue type data, etc.). Specifically, after the vascular object has been interrogated, the vascular object is cross-sectioned for histology. The cross-section is then prepared with a fixing and staining process that is well known in the art. The staining process allows a clinician to identify a tissue type(s). The identified tissue type (e.g., characterization data) is then provided to the characterization application and stored in the database.

In another embodiment of the present invention, the characterization application is further adapted to create a histology image and identify at least one corresponding region on the IVUS image. In this embodiment, digitized data corresponding to the cross-sectioned vascular object is provided to the characterization application. The digitized data is then used to create a histology image. A region of interest (ROI) on the histology image is then identified by the operator. Preferably, the ROI corresponds to the characterization data, as previously provided. The characterization application is then adapted to identify a corresponding region on the IVUS image. To accurately match the ROI, however, it may be necessary to warp or morph the histology image to

substantially fit the contour of the IVUS image. This warping removes histological preparation artifacts caused by cutting the tissue. Accordingly, in one embodiment of the present invention, the characterization application is further adapted to morph the histology image by (i) identifying (or receiving identifying data from an operator on) at least one landmark common to both the histology image and the IVUS image, (ii) use a first algorithm (e.g., a morphometric algorithm) to substantially align the corresponding landmarks, and (iii) use a second algorithm (e.g., a thin plate spline (TPS) deformation technique) to substantially align the non-landmark portions of the object.

In another embodiment of the present invention, the characterization application is further adapted to determine and store parameters associated with the ROI portion of the IVUS image. In this embodiment, the characterization application is adapted to identify the IVUS data that corresponds to the ROI on the IVUS image. After the IVUS data has been identified, and in accordance with one embodiment of the present invention, the characterization application is adapted to identify at least one parameter of the IVUS data. In another embodiment of the present invention, the characterization application is adapted to identify at least one parameter after frequency analysis has been performed (e.g., using fast Fourier transform, the Welch periodogram, autoregressive power spectrum (AR) analysis). The identified parameter is then stored in the database, where it is linked to the characterization data. This data (i.e., stored parameters and characterization data) can then be used to identify or characterize vascular tissue.

In a second embodiment of the present invention, the characterization application is adapted to receive IVUS data, determine parameters related thereto, and use the parameters stored in the database (i.e., histology data) to identify tissue type(s) or characterization(s) thereof. In this embodiment, the characterization application is adapted to receive IVUS data from the IVUS console and identify at least one parameter associated therewith (either directly or indirectly). In other words, the parameters may be identified directly from the IVUS data or from a transformation thereof (e.g., after frequency analysis). The identified parameters are then compared to

the parameters stored in the database (i.e., histology data). If a match (either exactly or substantially) is found, the related region is correlated to the tissue type (or characterization) stored in the database. In one embodiment of the present invention, the characterization application is further adapted to display a reconstructed image of the interrogated vascular object, where different tissue types are identified using different colors (e.g., discrete colors, gray-scales, etc.).

A more complete understanding of the system and method of using backscattered data and known parameters to characterize vascular tissue will be afforded to those skilled in the art, as well as a realization of additional advantages and objects thereof, by a consideration of the following detailed description of preferred embodiments. Reference will be made to the appended sheets of drawings which will first be described briefly.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a tissue-characterization system in accordance with one embodiment of the present invention, including an IVUS console, an IVUS catheter, a computing device and an input device.

Figure 2 illustrates an exemplary IVUS image.

Figure 3 illustrates a cross-section of an exemplary vascular object in-vivo and in-vitro.

Figure 4 illustrates an alternate embodiment of the computing device depicted in Figure 1.

Figure 5 illustrates an exemplary image of a characterized vascular object.

Figure 6 illustrates a method of characterizing a vascular object in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Preferred embodiments of the present invention operate in accordance with an ultrasonic device and a computing device comprising a characterization application and

a database. In the detailed description that follows, like element numerals are used to describe like elements illustrated in one or more figures.

Figure 1 illustrates a tissue-characterization system 10 operating in accordance with a first embodiment of the present invention. In this embodiment, an intra-vascular ultrasound (IVUS) console 110 is electrically connected to an IVUS catheter 120 and used to acquire RF backscattered data (i.e., IVUS data) from a blood vessel. Specifically, a transducer 122 is attached to the end of the catheter 120 and is carefully maneuvered through a patient's body to a point of interest. The transducer is then pulsed to acquire echoes or backscattered signals reflected from the tissue of the vascular object. Because different types and densities of tissue absorb and reflect the ultrasound pulse differently, the reflected data (i.e., IVUS data) can be used to image the vascular object. In other words, the IVUS data can be used (e.g., by the IVUS console 110) to create an IVUS image. An exemplary IVUS image 20 is provided in Figure 2, where the light and dark regions indicate different tissue types and/or densities. It should be appreciated that the IVUS console 110 depicted herein is not limited to any particular type of IVUS console, and includes all ultrasonic devices known to those skilled in the art (e.g., a C-VIS Clearview Imaging System, etc.). It should further be appreciated that the IVUS catheter 120 depicted herein is not limited to any particular type of catheter, and includes all ultrasonic catheters known to those skilled in the art. Thus, for example, a catheter having a single transducer (e.g., adapted for rotation) or an array of transducers (e.g., circumferentially positioned around the catheter) is within the spirit and scope of the present invention.

Referring back to Figure 1, the tissue-characterization system 10 further includes a computing device 130 comprising a database 134 and a characterization application 132 electrically connected to the database 134 and adapted to receive IVUS data from the IVUS console 110. It should be appreciated that the database 134 depicted herein includes, but is not limited to, RAM, cache memory, flash memory, magnetic disks, optical disks, removable disks, SCSI disks, IDE hard drives, tape drives and all other types of data storage devices (and combinations thereof, such as RAID devices)

generally known to those skilled in the art. It should further be appreciated that the characterization application 132, as depicted and discussed herein, may exist as a single application or as multiple applications, locally and/or remotely stored. It should also be appreciated that the number and location of the components depicted in Figure 1 are not intended to limit the present invention, and are merely provided to illustrate the environment in which the present invention may operate. Thus, for example, a computing device having a plurality of databases and/or a remotely located characterization application (either in part or in whole) is within the spirit and scope of the present invention.

In one embodiment of the present invention, the characterization application 132 is adapted to receive and store characterization data (e.g., tissue type, etc.). Specifically, after a vascular object has been interrogated (e.g., IVUS data has been collected), a histology correlation is prepared. In other words, the vascular object is dissected or cross-sectioned for histology. In one embodiment of the present invention, the cross-section is previously marked, for example with a suture, so that the histology can be corresponded to a portion of the IVUS image. The cross-section is then prepared with a fixing and staining process that is well known in the art. The staining process allows a clinician to identify a tissue type(s), or a chemical(s) found within (e.g., a chemical corresponding to a particular tissue type, etc.). It should be appreciated that the particular method used to identify or characterize the cross-sectional object is not a limitation of the present invention. Thus, all identification/characterization methods generally known to those skilled in the art are within the spirit and scope of the present invention.

The identified tissue type or characterization (i.e., characterization data) is then provided to the characterization application 132. In one embodiment, as shown in Figure 1, the characterization data is provided via an input device 140 electrically connected to the computing device 130. The characterization data is then stored in the database 134. It should be appreciated that the input device depicted herein includes, but is not limited to, a keyboard, a mouse, a scanner and all other data-gathering and/or

data-entry devices generally known to those skilled in the art. It should further be appreciated that the term tissue type or characterization, as these terms are used herein, include, but are not limited to, fibrous tissues, fibro-lipidic tissues, calcified necrotic tissues, calcific tissues, collagen compositions, cholesterol, thrombus, compositional structures (e.g., the lumen, the vessel wall, the medial-adventitial boundary, etc.) and all other identifiable characteristics generally known to those skilled in the art.

In one embodiment of the present invention, the characterization application is adapted to create a histology image and to identify at least one corresponding region on an IVUS image. Specifically, digitized data is provided to the characterization application (e.g., via the input device 140), where the digitized data corresponds to the cross-sectioned vascular object. The digitized data is then used to create a histology image (i.e., a digital image or outline that substantially corresponds to the vascular object). A region of interest (ROI) on the histology image can then be identified by the operator. Preferably, the ROI is characterized by the characterization data, as previously provided, and may be the entire histology image or a portion thereof. The characterization application is then adapted to identify a corresponding region (e.g., x,y coordinates, etc.) on the IVUS image (i.e., the image created using the raw backscattered data, or the IVUS data).

To accurately match the ROI, however, the histology image may need to be warped to substantially fit the contour of the IVUS image. The warping removes histological preparation artifacts caused by cutting and/or fixing the tissue. For example, as shown in Figure 3, the shape of a in-vivo vascular object 32 is generally round. Once this object is cut, or cross-sectioned for histology (i.e., creating an in-vitro vascular object 34), the object may appear somewhat distorted, or flattened. Furthermore, the tissue may shrink (e.g., about 30%) when it is put through the fixation process. Thus, in order to identify a corresponding ROI on the IVUS image, the histology image may need to be warped or morphed, to return it to its original shape.

Accordingly, in one embodiment of the present invention, the characterization application is adapted to morph the histology image. Specifically, the characterization application is adapted to identify (or receive identifying data from an operator on) at least one landmark common to both the histology image and the IVUS image (see e.g., Figure 3, landmark A). The characterization application is then adapted to use (i) a first algorithm (e.g., a morphometric algorithm) to substantially align the corresponding landmarks and (ii) a second algorithm (e.g., a thin plate spline (TPS) deformation technique) to substantially align the non-landmark portions of the object. In other words, the second algorithm is used to shape the regions or boundaries between the landmarks. It should be appreciated that the landmarks discussed herein include, but are not limited to, side branch vessels, identifiable plaque or calcium deposits, and all other vascular tissue landmarks generally known to those skilled in the art.

In one embodiment of the present invention, the characterization application is further adapted to determine and store parameters associated with the ROI portion of the IVUS image. Specifically, the characterization application is adapted to identify the IVUS data (i.e., the raw backscatter data) that corresponds to the ROI identified on the IVUS image. In other words, the IVUS data that was originally used to create the ROI on the IVUS image is identified. In one embodiment of the present invention, the characterization application is further adapted to identify at least one parameter of the identified IVUS data. This parameter is then stored in the database, where it is linked to the characterization data. It should be appreciated, however, that each parameter may be associated with more than one tissue type or characterizations. For example, a first parameter may be common to multiple tissue types, thus requiring additional parameters to narrow the field.

In another embodiment of the present invention, signal analysis (i.e., frequency analysis, etc.) is performed on the identified IVUS data before the parameters are identified. In other words, the IVUS data is converted (or transformed) into the frequency domain (e.g., from the time domain) to identify the frequency spectrum of the ROI. This is because the frequency information obtained from the backscattered signal

(or parameters associated therewith) can serve as a "signature" for each tissue type or characteristic. In one embodiment of the present invention, the frequency analysis is performed using a fast Fourier transform (FFT). In another embodiment of the present invention, the frequency analysis is performed using the Welch periodogram. In another embodiment of the present invention, the frequency analysis is performed using autoregressive power spectrum (AR) analysis. At least one parameter of the frequency-based signal is then identified and stored in the database, where it is linked to the characterization data.

In another embodiment of the present invention, both backscattered data (e.g., IVUS data) and its frequency spectrum are analyzed to classify the ROI portion of the IVUS image. Specifically, the frequency spectrum (or more particularly at least one parameter identified therefrom) is used to identify tissue type and the backscattered data is used to identify tissue location. This is because the backscatter data is in the time domain, and can thus be used to spatially identify certain frequencies (or parameters related thereto). For example, if a vascular wall comprises multiple tissue layers, corresponding backscattered data can be used to identify the location of these tissues and the related frequency spectrum can be used to identify tissue types. It should be appreciated that, while certain embodiments have been described in terms of frequency transformation, the present invention is not so limited. Thus, alternate transformations (e.g., wavelet transformation, etc.) are within the spirit and scope of the present invention. It should further be appreciated that the term parameter, as that term is used herein, includes, but is not limited to maximum power, minimum power, frequencies at maximum and/or minimum power, y intercepts (estimated or actual), slope, mid-band fit, integrated backscatter and all parameters generally known to (or discernable by) those skilled in the art. It should also be appreciated that the term "histology data," as that term is used herein, includes data stored in the database (e.g., characterization data, parameters, etc.).

One method of populating the database is illustrated in Figure 6. Specifically, at step 610, IVUS data (i.e., RF backscatter data) is collected from a portion of a vascular

object. This data is then used to create an IVUS image at step 612. At step 614, the interrogated portion of the vascular object is cross-sectioned and a tissue type (or a characterization thereof) is identified. This information (i.e., characterization data) is then transmitted to a computing device (or the equivalent thereof) at step 616. At step 5 618, an image of the cross-sectioned vascular object is created and a ROI is identified (e.g., by an operator). This image is then morphed, if needed, to substantially match the cross-section image to the IVUS image at step 620. This may include identifying at least one landmark and applying at least one algorithm (e.g., a morphometric algorithm, a TPS deformation technique, etc.). At step 622, the ROI is mapped to the IVUS image and associated IVUS data is identified. Spectral analysis is then performed on the 10 associated IVUS data at step 624, and at least one parameter is identified at step 626. The at least one parameter and the characterization data is then stored at step 628. In one embodiment of the present invention, the at least one parameter is stored such that it is linked to the characterization data. It should be appreciated that the order in which 15 these steps are presented is not intended to limit the present invention. Thus, for example, creating an IVUS image after the vascular object is cross-sectioned is within the spirit and scope of the present invention.

The above-described process is repeated for each tissue component desired to be identified and repeated for each component as many times as desired in order to 20 obtain a more accurate range of signal properties. With the database populated, a tissue type or characteristic can be automatically and accurately identified if the acquired parameters substantially match parameters stored in the database.

Accordingly, in a second embodiment of the present invention, the characterization application is adapted to receive IVUS data, determine parameters 25 related thereto, and use the parameters stored in the database (i.e., histology data) to identify tissue type(s) or characterization(s) thereof. Specifically, with reference to Figure 1, the characterization application 132 is adapted to receive IVUS data from the IVUS console 110. The characterization application 132 is then adapted to identify at least one parameter associated (either directly or indirectly) with the IVUS data. It

should be appreciated that the IVUS data may either be received in real-time (e.g., while the patient is in the operating room) or after a period of delay (e.g., via CD-ROM, etc.). It should further be appreciated that the identified parameters should be related (generally) to the stored parameters. Thus, for example, an estimated Y intercept parameter should be identified if data related to a signal's estimated Y intercept is stored in the database 134 and linked to at least one tissue type. Moreover, if the stored parameters were acquired after frequency analysis was performed (i.e., are related to a frequency-based signal), then frequency analysis (preferably of the same type) should be performed on the IVUS data before parameters are identified. However, the IVUS data may be used to identify spatial information, as previously discussed.

The identified parameters are then compared to the parameters stored in the database (i.e., histology data). If a match (either exactly or substantially) is found, the related region is correlated to the tissue type (or characterization) stored in the database 134 (e.g., as linked to the matching parameters). It should be appreciated that a match may occur as long as the parameters fall within a range of properties for a particular tissue type found in the database.

In one embodiment, after each region is identified, the characterization application is further adapted to display a reconstructed image of the interrogated vascular object on a display. A computing device 130 including such a display 136 is illustrated in Figure 4. In one embodiment of the present invention, each tissue type (or characterization) is distinguished through the use of gray-scales or discrete colors. For example, Figure 5 illustrates an exemplary reconstructed vascular object 510, where different tissues (e.g., calcific tissues 512, fibrous tissues 514, calcified necrotic tissues 516 and fibro-lipidic tissues 518) are identified using different shades of gray. Such a system makes different tissue types or characterizations easily identifiable. Additional examples of characterized vascular objects are provided by U.S. Patent Number 6,200,268, which was issued on March 13, 2001, and is incorporated herein, in its entirety, by reference. It should be appreciated that the reconstructed vascular object

may further identify vascular borders. Systems and methods of identifying vascular borders are provided by U.S. Provisional Application Numbers, 60/406,184, 60/406,234, and 60/406,185, which were filed August 26, 2002, and by U.S. Patent Number 6,381,350, which issued April 30, 2002, and are incorporated herein, in their entirety, by reference.

Having thus described embodiments of a system and method of using backscattered data and known parameters to characterize a vascular tissue, it should be apparent to those skilled in the art that certain advantages of the system have been achieved. It should also be appreciated that various modifications, adaptations, and alternative embodiments thereof may be made within the scope and spirit of the present invention. The invention is further defined by the following claims.